Testimony Before the Subcommittee on Health
Committee on Energy and Commerce

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"Helping the FDA Protect America's Food Supply"

April 24, 2008

Introduction

Mr. Chairman and members of the subcommittee, I am James Lovett, Corporate Senior Vice President for Covance Inc., one of the world's largest and most comprehensive contract research companies with global operations in more than 20 countries, and more than 8,700 employees worldwide (approximately two thirds in the United States). Our company conducts research and development for pharmaceutical companies and provides laboratory testing services to the chemical, agrochemical and food industries. I am responsible for Covance's food testing business. We are pleased to have been invited as part of this discussion on food safety, and look forward to working with the Committee as this process continues.

Overview of Covance's Work

Covance is a full service laboratory to the food industry offering comprehensive testing services for both food safety and food nutrition. The food testing organization originally grew from a research branch of the University of Wisconsin over 75 years ago. This

testing facility in Madison, Wisconsin, is now one of the largest food testing laboratories in the world. The total Covance campus in Madison covers nearly one million square feet of laboratories and employs almost 2,000 scientists and technicians, and food testing is an important part of our operation. In addition to the Madison laboratory, Covance operates food testing laboratories in Battle Creek, Michigan, and in Singapore.

The food testing laboratory in Madison can routinely analyze over 50,000 samples per month. It operates 24 hours a day, seven days a week. It provides rapid accurate test data to industry customers, as well as state and federal government agencies. The food safety testing programs employed at Covance cover testing protocols for chemical contamination, microbiological contamination, pathogen detection, and detection of other deleterious contaminants. The testing profile includes detection of the contamination, identification of the chemical or microbe, quantification of the contamination, and confirmation of all positive test data. Our laboratories in Michigan and Singapore feature similar capabilities. Covance has provided food testing support to FDA for many years on a wide variety of projects.

Current Status of Food Safety Testing at FDA

FDA regulates roughly 80 percent of the U.S. food supply which is $417 billion worth of domestic food and $49 billion in imported food annually.[1] FDA has oversight of more than 136,000 registered domestic food facilities. Approximately 189,000 registered foreign facilities manufacture, process, pack, or hold food consumed by Americans.

[1] FDA Food Protection Plan, Nov. 2007, p. 6.

FDA plays a critically important role in ensuring the safety and public confidence in the food we eat. Foodborne illnesses are caused by more than 200 different foodborne pathogens of which we are currently aware. These include viruses, bacteria, parasites, and toxins, plus a vast number of potential chemical contaminants and metals.

FDA's Food Protection Plan outlines many of the factors complicating its mission of protecting the safety of the U.S. food supply. Changes in demographics, convenience trends, and consumption patterns are converging in a way that poses new challenges for ensuring the safety of the foods we eat. In addition, the sheer volume, variety, and complexity of the FDA-regulated products arriving at U.S. ports makes it nearly impossible for FDA to adequately oversee compliance with food safety standards and FDA's regulations. According to FDA's report, over 300 U.S. ports receive products from the more than 150 countries and territories with whom the U.S. trades.[2]

FDA concedes in its Plan that "increases in the volume and complexity of imported foods have taxed the limits of FDA's approach to handling imports."[3] In response, FDA has recommended a new approach for addressing potential safety issues with imported foods, including increased intervention in the form of targeted, risk-based inspections and testing. FDA's plan supports the concept of accrediting highly qualified third parties to assist with this effort. FDA acknowledges it lacks the resources to adequately perform this function on its own. Furthermore, it understands that using qualified third parties will

[2] Id., p. 8.
[3] Id., p. 8.

allow this new approach to be implemented more quickly and efficiently than by simply increasing FDA's infrastructure and staff resources.

Covance believes that FDA is doing the best it can with the resources it has. However, the reality is that less than 1 percent of U.S. food imports are tested. This does not compare favorably to the 25 percent that is tested in Canada or the even higher percent that is tested in Japan. We believe a risk-based plan as suggested by the FDA offers the best general approach to improving food safety without having to test every last article of imported food. However, even under a risk-based approach, our nation should clearly be testing much more food than it currently does.

Even where good processes are believed to be in place to assure food safety, testing is the only way to be confident that those processes are actually working to produce and ship food that is safe for consumption by the American public. If you think about it, all food is tested – either in a laboratory before a human eats it or by the consumer at the actual time of consumption. We believe it is only prudent to have a robust testing program to ensure that the ultimate test – what happens when a human being eats the food – consistently results in a passing grade.

Benefits of a Third Party System to the American Public

Covance applauds the Committee for including within its draft bill a provision authorizing FDA to accredit third party laboratories. Authorizing FDA to accredit third

parties to assist in the efforts to institute a more rigorous, risk-based approach to food safety testing will provide the following benefits:

(1) Faster Implementation of New Food Safety Objectives

(2) Efficient Use of Limited Government Resources

(3) Access to State-of-the-Art Testing Facilities

(4) Ability of FDA to Maintain Adequate Oversight and Control

(1) *Faster Implementation* - This country currently has significant private laboratory capacity capable of quickly ramping up to meet any new testing requirements desired by Congress or FDA. There is no need for FDA to do this alone – with longer timelines to ramp up and higher cost to the U.S. taxpayer – when capable private laboratories can help.

(2) *Efficient Use of Limited Resources* - It's not necessary for FDA to dramatically increase its laboratory testing capabilities. This capacity currently exists in the private sector and we would be able quickly meet any new testing requirements.

(3) *Access to State-of-the-Art Testing Facilities* – Covance and many other highly qualified laboratories maintain "state of the art" equipment providing a high level of automation, ensuring very rapid and high volume sample through put. These sophisticated instruments provide the very highest level of sensitivity and selectivity, allowing our laboratories to provide extremely sensitive and precise test results. Our highly trained staff is able to report results faster than most other laboratories, including those currently operated by FDA.

(4) *Ability of FDA to Maintain Adequate Oversight and Control* - FDA has worked with independent laboratories for many years in the human and animal drug approval process, the new cosmetic approval process, and in the submission of new food additives. In our experience, this process has worked well. Expanding some of the existing relationships by providing FDA with authority to accredit third parties to expand food testing capacity would rightfully entail very strict accrediting requirements. Only laboratories able to demonstrate the ability to comply with very strict standards established by FDA should receive accreditation. FDA should conduct compliance audits to ensure all accredited laboratories maintain these high standards. By placing control within the FDA for accreditation on the front end, while providing auditing authority to ensure third party laboratories maintain the required standards, FDA will have the tools it needs to maintain adequate oversight of this new authority.

How a Comprehensive Third Party Testing System Would Work

For a typical food shipment that FDA has determined must receive testing at a port-of-entry, we believe the process might work as follows.

- When a food shipment arrives at a U.S. port, FDA or the importer would determine whether it should be subject to testing under FDA's new risk-based testing requirements. If a shipment is chosen for testing, the food would be sampled according to a strict sampling plan determined by FDA to arrive at a "statistically" valid sample. These samples could be taken by third party, independent sampling companies, several of which already exist.

- Samples would then be transferred to the third party laboratory – with the collected samples maintained under a "chain of custody" while they are transported.
- Samples would arrive at the laboratory and be "logged in" to the laboratory data system. At the same time, FDA and the private food company would be notified of sample arrival and given an estimate for data completion. Within hours of sample receipt, the laboratory could initiate testing.
- When test data is complete, results would be simultaneously transmitted to FDA and the food company. If any data show a presumptive positive for a pathogen or poisonous chemical, an investigation would be initiated immediately to confirm these results. Once again, notification would be sent simultaneously to FDA and the food company.
- The testing company would conduct the investigation to confirm the test data and final reports would be issued to FDA and the food company.

FDA Accreditation and Oversight of Third Party Labs

It is essential that the American public have a high level of confidence in accredited third party laboratories. Therefore, I would like to expand upon the FDA accreditation requirements that will be critical to an effective and efficient third party testing program.

The data produced by the independent laboratories will be used to make critical decisions about the quality of the U.S. food supply. Therefore, FDA must require rigorous standards and accreditation requirements for third party laboratories. We fully support the

provisions in the draft FDA Globalization Act which provide for the Secretary to accredit laboratories, monitor laboratory performance and conduct annual audits. I will discuss some of the requirements we would expect FDA to include within its accreditation standards. FDA might include other requirements as well.

FDA Good Laboratory Practices

In order to become a qualified third party testing laboratory, FDA must provide for laboratory accreditation and certification, and the laboratory must be able to produce acceptable data in the proficiency testing program. FDA should standardize the test methods being used so that comparable procedures would be used by all testing facilities. FDA already has published Good Laboratory Practices (FDA GLP) for third party laboratories and this protocol has been followed by a multitude of laboratories in their data submission to FDA for many years. FDA should continue to use this highly reliable standard, which is respected across the globe.

International Standards Organization (ISO) 17025 Standard

Another standard FDA might require as part of the accreditation process is ISO – the International Standards Organization – a European-based organization with a mission to standardize practices in a number of industries. ISO standards are used in manufacturing, in the chemical and petroleum industries, and in food processing. ISO's published test methods are often similar to AOAC, which I will discuss in a moment. In particular, the ISO 17025 standard was developed for laboratories and requires comprehensive documentation of laboratory activities in the form of Standard Operation Procedures

(SOP). The standard also requires a Quality Manual that describes overall business conduct. Companies are required to submit to an inspection for this accreditation, and must demonstrate acceptable testing performance in the form of an external sample evaluation program. Although not as comprehensive as the FDA GLP program, ISO 17025 is very effective in ensuring a laboratory keeps good records. Requiring ISO certification, together with the FDA GLP program, would be very effective in ensuring stringent record keeping requirements and the high standards for the measurement of the data quality.

AOAC International Official Methods

The majority of the testing methods currently used today have been fully validated and standardized by AOAC International and these methods would provide a uniform framework for the industry. Founded in 1884, AOAC provides validation services for testing methods including laboratory evaluation, proficiency testing, and validation of test methods which are globally recognized. AOAC Official Methods are considered the "gold standard" of test methods around the world, and are recognized by regulatory agencies and courts of law. FDA laboratories themselves use an AOAC method when it is available, and these standards are already used extensively in the food and dietary supplement industries. This aligns the FDA and third party laboratories very well. We recommend FDA require use of AOAC methods whenever they are available. FDA might also be encouraged to establish priorities for development of additional AOAC methods to meet new testing needs as they are identified.

Sampling Protocol

The draft bill indicated that the sampling and testing for a non-certified food company will be handled by an accredited testing laboratory. Currently a number of different models exist for conducting sampling. In order to ensure the efficacy of the test results, it is important that the sampling protocol be uniform and clearly established.

Conclusion

In conclusion, Covance applauds the Committee for including provisions in its draft bill authorizing FDA to accredit third party laboratories. We believe there is an appropriate role for independent third party laboratories in improving the safety of the U.S. food supply. Proper oversight by FDA will guard against any perceived conflicts of interest. Use of third parties will also permit FDA to more quickly and easily alter resource requirements based upon changing circumstances and needs. Other benefits as discussed above include the following:

(1) Faster Implementation of New Food Safety Objectives

(2) Efficient Use of Limited Resources

(3) Access To State-of-the-Art Testing Facilities

(4) Ability of FDA to Maintain Adequate Oversight and Control

I hope my testimony will prove useful as the Committee considers measures to enhance FDA's food safety testing capabilities. Thank you for the opportunity to testify and I would be pleased to answer any questions the Committee may have.